

Appl. No. 10/502,049  
Amendment dated: February 19, 2008  
Reply to OA of: October 19, 2007

### **REMARKS**

Applicants have amended the claims to more particularly define the invention taking into consideration the outstanding Official Action. The O-acyl sialic acid derivatives have been restricted to the acetyl group as fully supported by the Applicants specification as originally filed.

The rejection of claims 14-23, 25 and 27-28 under 35 U.S.C. 112, first paragraph for lack of enablement has been carefully considered but is most respectfully traversed in view of the amendments to the claims restricting sialic acid derivatives to the acetyl derivatives. Clearly, as now amended, the claims are fully enabled by the specification to one of ordinary skill in the art without undue experimentation. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 14-28 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention has been carefully considered but is most respectfully traversed in view of the formation of the claims and the level of one of ordinary skill in the art to which the invention pertains.

Claim 15 has been further amended in that the second alternative ii) has been canceled to clarify the claim. This is similarly true with respect to the amendments to claims 26 and 27.

With respect to the meaning of "V", attached hereto are two different formulas. The first carbohydrate shown there is attached to a carrier whereas the radical "V" in the second formula represents a OH-group.

In the first formula the radical "V" represents a connecting point to the carrier, see also page 5, last but one paragraph of the present application.

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The carrier which can be used is any known carrier. Said carrier does not have any specific pharmacological activity. It is just - as the name says - an anchor or a carrier respectively for the active group of the general formula II.

This carrier can of course also be a further carbohydrate group. As is known there exists a tremendous group of carbohydrate carriers to which the carbohydrate unit of the general formula I can be attached. Please note that only 1 of such carbohydrate unit but also 2, 3... many of such units can be attached to the same carrier.

The above comments also takes care of the Examiner's objection with respect to claim 15. The carrier cannot be a carbohydrate unit of the formula II since if the carrier would be (hypothetical approach) such a carbohydrate of the formula I then it would belong to the compound represented by the formula I and the number "n", which represents 1-50, would increase by 1.

As far as claim 15 under i) is concerned please note that the term "N-glycolyl" is correct. The abbreviation there given (i.e. NeuGc) stands for N-glycolyl neuraminic acid.

Claim 17 is directed to compounds which are attached to a carrier group "T" being lipophilic compounds. These lipophilic compounds possess terminal groups or head groups, respectively which are carbohydrate units of the formula II.

To Applicants knowledge the term "head unit" or "head group" is well known for men skilled in the art of chemistry. This is evident from a search of the internet for this term. A further term for such a group would be "terminal group" or "end group". The meaning of the term is clearly definite to one of ordinary skill in the art to which the invention pertains. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

With respect to the rejection of claim 20, it is common practice to leave the upper limit open. Applicants simply do not know said upper limit. It depends very much on the body weight and other factors. To Applicants knowledge it is common practice to leave this upper limit undefined and this does not render the claim indefinite to one of ordinary

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skill in the art. Accordingly, it is most respectfully requested that this rejection be withdrawn.

With respect to the rejection of claim 22, Applicants have deleted the limitations within the parenthesis and have added the term "whereby said composition is not human milk" in order to make this claim formally admissible.

With respect to the rejection of claim 25, Applicants wish to note that this claim shall just make clear that the composition claimed does not only contain the carbohydrates of the formula I but may contain other known active compounds and/or usual ingredients. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants most respectfully submit that all of the claims now present in the application are in fully compliance with 35 USC 112 and are clearly patentable over the references of record.

The provisional rejection of claim 10 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 7 of co-pending Application No. 10/148,193 has been carefully considered but is most respectfully traversed. It is noted that these are provisional rejections and therefore it is most respectfully requested that any requirement for filing a Terminal Disclaimer with respect to these applications be held in abeyance until there is an indication of allowable subject matter in one of the applications and then appropriate action will be taken therein.

The rejection of claim 10 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 6 and 9-10 of U.S. Patent No. 6,576,251 has been carefully considered but is most respectfully traversed. Applicants most respectfully submit that the '251 patent deals with carbohydrate mixtures for foods and pharmaceuticals wherein the carbohydrates have a different chain length (certain mono, di- and polysaccharide distribution). Furthermore, fucose has to be present which is

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nowhere mentioned in the present application. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 14-28 under 35 U.S.C. 103(a) as being unpatentable over Gilbert et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments.

The Gilbert reference describes gangliosides and therefore carbohydrates which fall under the general formula I in claim 1.

As can be seen from the paragraph "field of the invention" on page 1 of the Gilbert reference, this reference is concerned with the enzymatic synthesis of oligosaccharides including gangliosides and gangliosides mimics.

The main focus of the Gilbert reference lies therefore on the synthesis of the compounds there described and not on the pharmacological activities of these compounds as would be appreciated by one of ordinary skill in the art to which the invention pertains. This becomes clearly evident from the claims of the Gilbert reference since none of the claims is directed to a pharmaceutical composition or to the use of the compounds described in the Gilbert reference for any particular pharmaceutical activity.

However, the Gilbert reference contains a section E which starts on page 42 of the Gilbert reference and deals with the possible utility of the compounds which can be obtained by the synthesis described in the Gilbert reference:

There it is for instance pointed out that compounds as produced by the teaching of the Gilbert reference can be used as antigens, diagnostic reagents or as therapeutics.

This teaching is extremely broad. As far as the conditions are concerned which can be treated by the pharmaceutical compositions there mentioned it is just pointed out that the pharmaceutical compositions can be used for treating a variety of conditions. This is not a clear technical teaching but just an assumption.

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Further explanations of the field of interest for the pharmaceutical compositions taught by the Gilbert reference can be found on page 42, starting at line 21. The explanations there given are of general nature and do not represent a concrete teaching but rather dreams/wishes.

The concrete teaching of the Gilbert reference starts on page 43, line 7. There it is stated that the oligosaccharides described in the Gilbert reference can be used for instance as diagnostic reagents.

If one compares this field with the pharmacological field of the present invention, i. e. immunomodulation, immunosuppression, prevention or treatment of infections, then it becomes clear that the field of interest of the present invention is not only novel but also unobvious with respect to the field of the diagnostic reagents. A diagnostic reagent is not a pharmaceutical composition for treating the above mentioned conditions.

Furthermore it is described in the Gilbert reference beginning on page 43, line 7 that the oligosaccharides as taught by the Gilbert reference can be used as an immunogen for the production of monoclonal or polyclonal antibodies.

The carbohydrates as used according to the present invention do not serve the purpose of producing antibodies. They are rather compounds used for medicinal purposes. A composition for producing an antibody is not a means for the immunomodulation, immunosuppression or prevention as well as treatment of infections of human beings and animals. According to the teaching of the Gilbert reference it is necessary to first prepare the antibodies by using the oligosaccharides there described. Said antibodies can then be used for medicinal purposes.

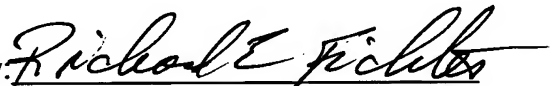
The Gilbert-reference does not disclose any specific therapeutic use of the oligosaccharides there describes. It just contains the very general teaching that the compositions can be administered for prophylactic and/or therapeutic treatments, see page 42, lines 21 and 22.

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If one would apply Examiner's reasoning then this general teaching would make all possible concrete therapeutic uses or fields, respectively, of the there described oligosaccharides as not inventive. Such an approach is not admissible. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,  
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